

REMARKS

Claims 36-41, 68-73, and 76-79 are pending in the application. Claims 1-35 and 42-67 have been cancelled by previous amendments. New claims 77-79 have been added. No new matter has been added.

Rejections Pursuant to 35 U.S.C. § 102

A. *Zanzucchi, et al.*

Claims 36-41 and 69-76 stand rejected pursuant to 35 U.S.C. § 102 as anticipated by *Zanzucchi, et al.*, U.S. Patent No. 5,593,838 (hereinafter "*Zanzucchi, et al.*"). Applicants respectfully disagree with the rejection because *Zanzucchi, et al.* does not teach each and every element of independent claims 36 and 72.

For example, contrary to the Examiner's interpretation of *Zanzucchi, et al.*, this reference does not teach a binding space that includes at least a part of an amplification space. The Examiner is of the opinion that the connecting channel (38)¹ that connects the first well (36) and second well (40) of *Zanzucchi, et al.* is the part of the binding space that is identical to the part of the amplification space. *Zanzucchi, et al.*, however, does not teach that the connecting channel participates in either binding or amplification. The only teaching in *Zanzucchi, et al.* about the connecting channel is that it moves the sample from the first well to the second well. The Examiner has not explained how this connecting channel participates in either binding or amplification.

Similarly, with regard to claim 38, the Examiner has interpreted the connecting channel (38) in *Zanzucchi, et al.* as part of the detection space, which *Zanzucchi, et al.* describes as a "third well," that is at least a part of the binding space and the amplification space. This interpretation is completely inaccurate. The channel that connects the first well and second well of *Zanzucchi, et al.* is different than the channel that connects the second well and the third well. It is totally unclear how the Examiner can find that two separate channels and three separate wells are all part of the same space

¹ The Office Action refers the "connecting channel" (38) as a "capillary channel."

as claimed. The Examiner states that the wells are interconnected to facilitate the flow of fluids, but that does not explain the Examiner's interpretation that all three wells are partially the same.

With regard to claims 39 and 40, the Examiner finds that col. 6, lines 59-67 of Zanzucchi, *et al.* show a capillary reaction vessel surrounded by a heatable metal layer. This interpretation is inaccurate for several reasons. Zanzucchi, *et al.* teaches that the wells are square or rectangular. *See* col. 6, line 67. Therefore, none of the wells described in Zanzucchi, *et al.* comprise a capillary space as recited in claim 39, and those wells are not a capillary reaction vessel as recited in claim 40. Also, specifically with regard to claim 40, the metal layers of gold and chromium described in col. 6, line 59 – col. 7, line 18 of Zanzucchi, *et al.* do not surround the wells. Instead, the metal layers are the top and bottom of a glass substrate. Thus, after the square or rectangular wells are etched in the substrate, the metal does not surround the wells. Moreover, the metal is removed after the wells are etched. *See* col. 7, lines 15-18. For all these reasons, Zanzucchi, *et al.* does not anticipate claim 40.

With regard to claim 72, the Applicants have amended (January 9 Amendment) the claim to recite the elements of cancelled claims 74 and 75. Therefore, claim 72 now recites “a capillary reaction vessel surrounded by a heatable metal layer.” As addressed above, Zanzucchi, *et al.* does not teach a capillary reaction vessel surrounded by a metal layer. Accordingly, claim 72 is not anticipated by Zanzucchi, *et al.*

With regard to claims 37, 41, 69, 70, and 71, which all depend directly or ultimately from claim 36, and claims 73, 76, which depend from claim 72, all of these claims include all of the elements of independent claims 36 or 72. Therefore, Zanzucchi, *et al.* does not anticipate these claims for the same reasons that Zanzucchi, *et al.* does not anticipate claims 36 and 72.

Claims 74 and 75 have been cancelled. Therefore, the rejection of those claims is now moot.

For all of the foregoing reasons, Applicants submit that the rejection of claims 36-41, and 69-76 over Zanzucchi, *et al.* should be withdrawn.

B. Yasuda, *et al.*

Claims 36-41, and 68-76 stand rejected under 35 U.S.C. § 102(e) over Yasuda, *et al.* (U.S. Patent No. 6,093,370). Applicants respectfully disagree.

The Examiner cites to col. 9, lines 5-36 as teaching a binding spaces which comprises at least a part of the amplification space as recited in claim 36. Here, however, Yasuda, *et al.* teach three separate “sample solution chambers” (731, 732 and 733), which are partitioned by a plurality of spacers (723). Sample solution is transferred between the chambers through the communication holes (714 and 715). It is unclear from the Examiner’s explanation of this disclosure how three partitioned chambers teach a “binding space compris[ing] at least a part of the amplification space.” Moreover, the discussion in col. 9, lines 27-36 teaches that the temperature of each of the chambers can be individually controlled. This disclosure clearly teaches that no part of the binding space can be a part of the amplification space.

The Examiner also cites to col. 22, lines 28-36 of Yasuda, *et al.* as teaching at least a part of the binding space is identical to at least a part of the amplification space. It is completely unclear, however, how this disclosure supports the Examiner’s conclusion. This disclosure is part of claim 2 of the Yasuda, *et al.*, which is directed to a “polynucleotide separation apparatus.” There is no teaching of amplification of nucleic acids in this disclosure.

The Examiner also cites to col. 17, lines 11-27 of Yasuda, *et al.* as teaching “at least a part of the amplification space is identical to at least a part of the binding space.” Like claim 22 of Yasuda, *et al.*, this disclosure refers to a “polynucleotide separation module” (431), which is described at col. 16, lines 32-48. Nucleic acids can be bound in the polynucleotide separation module, but there is no teaching in either col. 16 or col. 17 that polynucleotides are amplified in the module 431. In fact, col. 16, lines 23-27 teach

that the polynucleotides are “supplied to aftertreatment process 431 [*sic* 441]² including PCR amplification.” Thus, the polynucleotide separation module, which the Applicants understand the Examiner has interpreted as a “binding space,” is not partially identical to the aftertreatment process, which Applicants understand that the Examiner has interpreted to be an amplification space. Accordingly, this disclosure does not anticipate claim 36.

With regard to claim 38, the Examiner asserts that column 9, lines 5-40 of Yasuda, *et al.* teaches a detection space that is at least a part of the binding space and the amplification space. As addressed above, however, this disclosure is directed to three separate solution chambers. Therefore, the disclosure does not anticipate claim 38.

With regard to claim 40, the Examiner asserts that col. 16, lines 33-36 and Figs. 20 and 21 of Yasuda, *et al.* teach a capillary reaction vessel surrounded by a heatable metal layer. This disclosure in Yasuda, *et al.*, however, teaches a metal layer on the inside of the capillary wall 412. This is not a disclosure of a coating *surrounding* the vessel because the coating cannot surround the *vessel* if the coating is on the *inside* of the vessel.

Similarly, with regard to claim 68, the Examiner cites to col. 16, lines 29-48, Figs. 20 and 21, and col. 23, lines 11-34, as teaching a capillary reaction vessel surrounded by a single heatable metal layer. Again, the disclosure in column 16 teaches that the metal layer is coated on the inside wall of the vessel, but does not surround the capillary reaction vessel as claimed. With regard to the disclosure in col. 23 of Yasuda, *et al.*, the Applicants do not understand how this disclosure supports the Examiner’s argument. To the extent that the Examiner intends that this disclosure is relevant to the “heatable metal layer,” the disclosure does not add anything in addition to the other disclosure cited by the Examiner.

² Fig. 23 of Yasuda, *et al.* shows that the solution extracted from module 431 passes to the capillary connection unit 433 to the aftertreatment process 441. The reference to the aftertreatment process as element 431 in col. 17, line 26 of Yasuda, *et al.* appears to be a typo or printing error.

With regard to claim 72, for the reasons stated above, Yasuda, *et al.* does not teach a capillary reaction vessel surrounded by a heatable metal layer as presently recited in claim 72. Accordingly, Yasuda, *et al.* does not anticipate claims 72.

With regard to claims 37, 41, 69, 70, and 71, which all depend directly or ultimately from claim 36, and claims 73, 76, which depend from claim 72, all of these claims include all of the elements of independent claims 36 or 72. Therefore, Yasuda, *et al.* does not anticipate these claims for the same reasons that Yasuda, *et al.* does not anticipate claims 36 and 72.

Claims 74 and 75 have been cancelled. Therefore, the rejection of those claims is now moot.

C. Andresen *et al.*

Claim 68 stands rejected under 35 U.S.C. § 102(e) as anticipated by Andresen *et al.* (U.S. Patent No. 6,126,804). According to the Examiner, col. 7, lines 30-67, and col. 8, lines 1-4 and 13-22 of Andresen *et al.* teach a capillary reaction vessel surrounded by a single heatable metal layer that is coated on the vessel. Applicants respectfully disagree.

Andresen *et al.* teaches that the coating of an electrically conductive material is applied to the inside and bottom portions of a well for PCR and to the end section of the capillary electrophoresis column that connects to the well. *See* col. 4, lines 38-40 and col. 5, lines 56-59, referring to element 27 of Fig. 2B. The metal layer is not applied to the cover plate 25, which covers the wells and the column. *Id.* The metal layer of Andresen *et al.*, therefore, does not surround a capillary reaction vessel as presently recited in claim 68. Applicants, therefore, request that the rejection of claim 68 over Andresen *et al.* be withdrawn.

D. Fields

Claim 36-38 and 69-73 stand rejected under 35 U.S.C. § 102(e) as anticipated by Fields (U.S. Patent Publication No. 2003/0027203).

With regard to claim 36, the Examiner cites to ¶¶ 0027, 0060-0061 and 0063, and Figs. 5 and 6, as teaching “a binding space comprising at least a part of the amplification space.” The Examiner explains this interpretation by stating that the vial 420 is connected to the amplification space by capillary tubes. The Examiner, however, has incorrectly applied Fields to the presently claimed invention.

Fields teaches an apparatus where nucleic acids are liberated in incubation chamber 15 (*see* ¶ 0060). The lysate solution containing the nucleic acids is transferred to and passed through the target molecule absorption filter 21 to which the nucleic acids bind (*see* ¶ 0061). The nucleic acids are washed from the filter and transferred to device 430 for PCR amplification (*see* ¶ 0063). Contrary to the Examiner’s interpretation, Fields does not teach that a part of the binding space is identical to a part of the amplification space. The binding space in Fields is the target molecule absorption filter 21. No amplification takes place in the vicinity of this filter. Instead, Fields teaches that the nucleic acids are washed from the filter and transferred to device 430 for PCR amplification. Therefore, the binding space and the amplification space in Fields are completely independent.

It appears that the Examiner correctly recognizes that Fields teaches the purification of nucleic acids in one vessel (*e.g.* ¶ 0060, incubation chamber 15) and the purified content is moved to a separate vessel by a “capillary tube.” While Applicants agree that FIG. 6 shows that the nucleic acids are moved via a tube from the purification vessel to an amplification vessel, the disclosure does not describe the tube as a “capillary tube” like the Examiner does. Applicants object to the Examiner’s embellishment of the disclosure of Fields. In any event, as Applicants understand the discussion from the interview on August 12, 2005 and November 3, 2005, the Examiner is of the opinion that the capillary tube is both part of the binding space and the amplification space. This conclusion is inaccurate because Fields does not teach that either the binding or the amplification occurs in the tube.

With regard to claim 38, the Examiner concludes that detection space comprises at least a part of the binding space or the amplification space by reference to FIGs. 1-3

and 6, which show interconnection of the spaces by three-way and four-way valves. The Examiner's conclusion can not be correct, however, because the spaces can not be at least partially identical if they are connected through one or more valves. Again, Fields does not teach that binding, amplification and detection all occur in the same space.

With regard to the rejection of claim 72, the claim has been amended (January 9 Amendment) to recite that the binding space comprises a capillary reaction vessel surrounded by a heatable metal layer. The Examiner, however, does not assert that Fields *et al.* teaches this element. Therefore, the rejection of claim 72 is moot.

With regard to claims 37, 69, 70, and 71, which all depend directly or ultimately from claim 36, and claim 73 which depends from claim 72, all of these claims include all of the elements of independent claims 36 or 72. Therefore, Fields does not anticipate these claims for the same reasons that Fields does not anticipate claims 36 and 72.

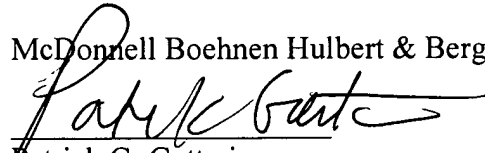
For all of the foregoing reasons, Applicants submit that the rejection of claims 36-38, and 69-73 over Fields should be withdrawn.

CONCLUSION

With the above amendments and remarks, Applicants respectfully submit that the application is in condition for allowance. If Examiner is of the opinion that a telephone conference would expedite prosecution of the application, Examiner is encouraged to contact Applicants' undersigned representative.

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